skilled in the art at the time the invention was made to modify the invention of Kardys in view of Tipton *et al.* into the objects of the instant application.

Applicants traverse this rejection. Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention absent some motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the Applicant. The cited references, by themselves, must teach or suggest the claimed invention and provide the motivation to combine the references in the manner necessary to produce the claimed invention. It is impermissible to engage in a hindsight reconstruction of the claimed invention, using the Applicant's disclosure as a template and selecting elements from references to fill the gaps.

The present rejection does not establish a *prima facie* case of obviousness with respect to the invention of claims 1-9. As discussed below, both of the referenced cited by the Examiner relate to different types of compositions and the references, therefore, cannot be combined in the manner suggested by the Examiner.

The Kardys patent teaches a vitamin composition for ingestion which consists essentially of 25% to 55% by weight of an oil-soluble vitamin selected from the group consisting of vitamin A, vitamin D_2, vitamin D_3, vitamin E or combinations thereof, in water together with a specific dispersing agent which makes up about 50% to about 85% of the total composition. The dispersing agent is a mixture of polyoxyethylene sorbitan monooleate and an ester selected from polyethylene glycol 400 monooleate, decaglycerol dioleate , and decaglycerol tetraoleate. The ratio of the polyoxyethylene sorbitan monooleate to the ester is from about 1:3 to about 3:1 by weight. Kardys does not teach inclusion in the formulation of a C_1 to C_6 alkyl lactate, a component of vitamin compositions of claims 1-9.

The Tipton *et al.* patent discloses compositions useful for the controlled release of substances wherein the compositions comprise a non-polymeric, non-water soluble high-viscosity liquid carrier material of viscosity of at least 5,000 cP at 37 C that does not crystallize neat under ambient or physiological conditions and a substance to be delivered. The carrier material can be mixed with a viscosity lowering water soluble or miscible solvent to form a lower viscosity liquid carrier material and mixed with the substance to be delivered prior to

administration (Col. 2, lines 47-58). The patent discloses that the lower viscosity composition is easier to place in the body because it flows more easily into and out of syringes or implementation means and can be easily formatted as an emulsion (Col. 5, lines 54-58). On administration, the lower viscosity composition is placed into the body or on a surface, and the solvent dissipates or diffuses away from the composition forming, in-situ, a highly viscous implant or composition that releases the substance over time. The compositions are useful for the delivery of substances and for other applications, including the coating of tissue and prevention of adhesions. The substance to be delivered can be a biologically active substance which is defined as an organic molecule (Col. 6, lines 50-65). Vitamins, and in particular vitamins E and C, are disclosed as types of organic molecules in a list that includes proteins, drugs, carbohydrates, genes, lipids and hormones. Ethyl lactate is disclosed as a solvent that can be mixed with the high-viscosity liquid carrier material.

The compositions of each of the cited references are suitable for different and distinct uses (i.e., for ingestion and for controlled-release of substances). Neither of the references teaches that the compositions of that reference are suitable for any other use. Accordingly, the teachings of the cited references are too different to be combined in the manner suggested by the Examiner.

Even if it were somehow possible to combine the cited references, the Examiner has not established that an artisan of ordinary skill would have been motivated to combine the cited references in the manner suggested in the present Office Action.

The motivation for combining the two references provided by the Examiner in the present rejection indicated that one of ordinary skill in the art would seek to resolve the deficiency of the Kardys patent by adding ethyl lactate to the formulation, being motivated to do so as a way of controlling the viscosity of the composition, as well a producing a composition that can be more easily formulated as a emulsion or dispersion, as disclosed by the Tipton *et al.* patent.

Applicants submit, however, that the cited references do not provide motivation for combining their teachings in the manner suggested by the Examiner. The formulation disclosed in Kardys rapidly disperses in water (Col. 2, lines 4-5), and there is no mention in the patent of a need to control viscosity of the formulation. One skilled in the art would have no reason or

incentive to add ethyl lactate to the Kardys formulation to solve the problem of controlling viscosity as asserted by the Examiner when such a problem with the Kardys formulation was not disclosed or suggested.

Persons skilled in the art looking to develop a vitamin formulation would be unlikely to look to Tipton *et al.* for guidance. Tipton *et al.* is not generally directed to vitamin formulations. Tipton *et al.* is concerned with a composition for controlled release of a biologically active substance wherein the composition contains a non-polymeric non-water soluble high viscosity liquid carrier material. In some embodiments, where the high viscosity of the formulation may pose problems for delivery to the site of action, a solvent is added to the formulation to lower the viscosity of the carrier material. Although the patent discloses vitamins E and C as types of organic molecules useful in the formulation, vitamins are only one of a myriad of at least 20 types of compounds in a list spanning 13 lines (Col. 6, lines 53-65). There is nothing in this list that would suggest vitamins are in any way more appropriate that the other 18 possibilities. Additionally, Tipton *et al.* fails to disclose a specific composition or example containing a vitamin.

Furthermore, even if a person skilled in the art were to consider Tipton *et al.*, this patent covers so many possible components, including solvents and additives, such as biodegradable polymers, non-biodegradable polymers, fats and oils, that it is not readily apparent that a vitamin composition could or should contain an alkyl lactate. The lists of solvents alone include at least twenty possibilities, one of which is ethyl lactate (Col. 2, lines 47-56, and Col, 10, lines 15-23). However, there is nothing in the lists that suggests ethyl lactate would be any more appropriate for vitamin formulations than any other solvent in the list. Combining the teachings of Kardys and Tipton *et al.* would require a considerable amount of analysis to even reach the possibility of a vitamin composition over the many other possible combinations and even more unlikely is the discovery of a vitamin composition containing an alkyl lactate as required by claims 1-9.

The cited references, by themselves, must teach or suggest the claimed invention and provide the motivation to combine the references in the manner necessary to produce the claimed invention. To point to portions of the cited references that teach certain elements of the claimed invention and then state that the combination of all these elements would be obvious to obtain a

formulation having the properties that are described in the present application is a classic example of hindsight reconstruction and is improper.

The combination of the formulation of Kardys with ethyl lactate from Tipton *et al.* could only be obtained by improper hindsight reconstruction using the disclosures of the present application as a template. There is no motivation or incentive in Kardys or Tipton *et al.* to modify the formulation of Kardys by adding ethyl lactate disclosed in Tipton *et al.* to provide formulations of claims 1-9. Accordingly, it is submitted that the Examiner has failed to establish a *prima facie* case of obviousness. Claims 1-9 are therefore not obvious over Kardys in view of Tipton *et al.* Withdrawal of this section 103 rejection is requested.

In view of the above, the present application is believed to be in a condition ready for allowance. Reconsideration of the application is respectfully requested and an early Notice of Allowance is earnestly solicited.

Respectfully submitted,
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